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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,118	02/09/2006	Nicolas Beaudet	1912-0316PUS1	1706

2292 7590 12/09/2010

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EXAMINER	
SCHMIDTMANN, BAHAR	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
12/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/537,118	BEAUDET ET AL.	
	Examiner	Art Unit	
	BAHAR SCHMIDTMANN	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-34,39 and 40* is/are pending in the application.

4a) Of the above claim(s) *7-18,20-28,31-34 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6,19,29,30 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's Amendment and Remarks filed on 30 September 2010 in which claims 35-38 were canceled, claims 1, 4-29, 32, 34, 39 and 40 were amended.

Claims 1, 4-34, 39 and 40 are pending in the current application. Claims 7-18, 20-28, 31-34 and 39 are withdrawn as being drawn to a non-elected invention. Claims 1, 4-6, 19, 29, 30 and 40 are examined on the merits herein.

Withdrawn Rejections

The rejection of claims 1, 4-6, 19, 29, 30 and 40 under 35 U.S.C. § 103(a), as being obvious over Simard et al. (US Patent Application Publication No. 2006/0057131) in view of Campbell et al.; and over Abraham et al. as evidenced by Micheli et al. and Maeda et al. in view of Jolly et al. and Campbell et al. are withdrawn in view of the new 112, first and second rejections, below.

The rejections are hereby **withdrawn**.

Applicant's amendment, filed 30 September 2010, with respect to the rejections of claims 1, 4-6, 19, 29, 30 and 40 under 35 U.S.C. § 112, second paragraph, for indefiniteness, has been fully considered and is persuasive.

- The claims have been amended to replace the recitation "system" with "composition".

- The claims have been amended to recite "exopolysaccharide micelles comprising exopolysaccharide", so that it is clear the exopolysacharides are a part of the micelle itself.
- Claim 1 has been amended to delete the recitation "*Candida kefyr* and *Candida norvegensis*"

The claim as amended is supported in Applicant's Specification.

The rejections are hereby **withdrawn**.

Applicant and the assignee of this application are required under 37 CFR 1.105 to provide the following information that the examiner has determined is reasonably necessary to the examination of this application.

In response to this requirement, please provide a list of keywords, ATCC accession numbers, other names by which the bacterial strains are known in the art, or any other identifying information by which one skilled in the art would be able to distinguish the claimed strains, that are particularly helpful in locating publications related to the disclosed art of *Lactobacillus* strains R2C2, Inix, Esl and K2.

Additionally, if applicable, in response to this requirement, please provide the names of any products or services that have incorporated the claimed subject matter.

This requirement is an attachment of the enclosed Office action. A complete reply to the enclosed Office action must include a complete reply to this requirement. The time period for reply to this requirement coincides with the time period for reply to the enclosed Office action.

New Rejections

Claim Rejections - 35 USC § 112, first paragraph, enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6, 19, 29, 30 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The nature of the invention is drawn towards exopolysaccharide (EPS) micelles containing active agents within the core of the micelle. The EPS are produced by lactic

acid bacteria strains "*Lactobacillus* strains R2C2, Inix, Esl and K2". The active agents include DNA, RNA, protein, peptide, peptidomimetic, virus, bacteria, nutriceutical products and pharmaceutical agents.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(2) The state of the prior art/ (4) The predictability or unpredictability of the art:

Yang et al. (Academic Dissertation, 2000, cited in PTO-892) teaches dairy lactic acid bacteria produce antimicrobial compounds and EPS (p.3, first paragraph). Yang et al. teaches the polysaccharides produced by lactic acid bacteria can be in the form of a capsule, i.e. broadly and reasonably can be interpreted as a micelle (p.16, *2.4. Exopolysaccharides produced by LAB*). Yang et al. teaches the polysaccharides produced include dextrans of various branching and size (pp.16-17, *2.4.1. Homopolysaccharides*), with differing physical properties such as water solubility (p.27, *2.7.2. EPSs in food applications*, second paragraph). Yang et al. also teaches that lactic acid bacteria can produce heteropolysaccharides (p.17, *2.4.2. Heteropolysaccharides*). Additionally, Yang et al. teaches that of 600 lactic acid bacterial strains screened by van den Berg et al., only 30 were found to produce EPS (p.28, second paragraph). Yang et al. further identified ten strains of lactic acid bacteria that produced neutral or anionic EPS (p.38, *5.2. EPSs produced by LAB (III-V, unpublished results)*). Yang et al. also teaches that the exopolysaccharides produced differs amongst the different strains of the lactobacillus (p.18, table 2) as well as by a single strain (p.40, *5.2.1.2. Structural variations among the EPSs produced by Lb.*

helveticus strains), demonstrating that the products produced by these bacteria are highly unpredictable.

(5) The breadth of the claims:

The breadth of the claims is drawn towards a micelle shaped structure, wherein the polysaccharide is a constituent of said micelle, and produced by "*Lactobacillus* strains R2C2, Inix, Esl and K2".

(6) The amount of direction or guidance presented:

The instant specification states that the exopolysaccharides can form micelles, wherein the EPS "can be isolated from, but not limited to *Lactobacillus* strains R2C2, *Lactobacillus* Inix, *Lactobacillus* Esl, *Lactobacillus* K2" (p.10, lines 9-13). The specification teaches that the size of the micelles can range from 50 to 700nm (p.10, lines 9-13). However, the instant specification does not disclose any ATCC numbers or other identifying information for the instantly claimed bacterial strains. The names in the instant application appear to be idiosyncratic and there is no publically available source for these bacteria.

(7) The presence or absence of working examples:

The instant specification discloses working examples, which includes the extraction of EPS from a biomass of a consortium of bacteria that includes *Lactobacillus* strains R2C2, *Lactobacillus* Inix, *Lactobacillus* Esl, *Lactobacillus* K2 (see p.10, example 1, lines 20-25). The specification teaches treating the biomass of bacteria or purified bacterial strain to obtain a final precipitate comprising the exopolysaccharide (pp.10-11, examples 2-4).

Besides molecular weight, there is no guidance on the structure of the polysaccharide or how one having ordinary skill in the art would be able to determine the structure of the polysaccharide. As a result, one having ordinary skill in the art would not be able to determine if they have obtained and/or are using the same polysaccharide as recited in the claims and specification.

It should be noted that there is no guidance or working example on how to obtain the pure bacterial strains, i.e. the claimed strains, to enable one of ordinary skill in the art to produce the claimed EPSs.

(8) The quantity of experimentation necessary: In order to practice the invention with the full range of possible exopolysaccharides beyond those known in the art, one skilled in the art would undertake a novel and extensive research program to isolate and identify the claimed bacterial strains and isolate and identify the polysaccharide capable of forming a micelle with the claimed active agents. Without the disclosure of any experimentation in the instant specification on how to obtain the claimed bacterial strains, it is literally impossible to make and use the claimed invention, constituting an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for making and using EPS micelles produced from lactic acid bacteria.

Claim Rejections - 35 USC § 112, first paragraph, written description

Claims 1, 4-6, 19, 29, 30 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are directed towards obtaining exopolysaccharides from *Lactobacillus* strains R2C2, Inix, Esl and K2. However, the instant specification has not provided how to obtain the claimed biological material, i.e. the lactobacillus strains or any structural information on the exopolysaccharide itself.

According to MPEP 2163: "Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., Pfaff v. Wells Elecs., Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991)

In the instant case no drawings, structures, chemical formulae, or other identifying characteristics are provided.

According to MPEP 2402, with respect to biological material:

Every patent must contain a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention. Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material may be necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated: "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); In re Gostelli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

According to MPEP 2163: The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP § 2163. The MPEP does state that for a generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP § 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP § 2163. Although the MPEP does not define what constitute a sufficient number of representative species, the courts have indicated what do not constitute a representative number of species to adequately describe a broad generic. In *Gostelli*, the courts determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. *In re Gostelli*, 872, F.2d at 1012, 10 USPQ2d at 1618.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient."

MPEP § 2163. While all of the factors have been considered, a sufficient amount for a *prima facie* case is discussed below.

In the instant case, the claims are drawn towards exopolysaccharide micelles containing active agents within the core of the micelle. The exopolysaccharides are produced by lactic acid bacteria strains R2C2, Inix, Esl and K2. The active agents include DNA, RNA, protein, peptide, peptidomimetic, virus, bacteria, nutriceutical products and pharmaceutical agents.

(1) Level of skill and knowledge in the art:

The relative skill of those in the art is high.

(2) Partial structure:

With respect to the lactobacillus strains, there is no information on whether or not they have been deposited. If they have been deposited, the accession numbers have not been provided. This is critical for fulfilling the written description requirement, so that one having ordinary skill in the art would be able to make and use the invention.

With respect to the exopolysaccharides produced by the claimed lactobacillus strains, the only information on their structure is the molecular weight. There is no information on the monosaccharide units, if the polysaccharide is a homopolysaccharide or a heteropolysaccharide, how the saccharide units are bonded to each other, and how many repeating units are present. There also is no information on the hydrophobic portion of the structure, which is essential to form a micelle.

(3) Physical and/or chemical properties and (4) Functional characteristics:

With respect to lactobacillus strains, there is no information on its physical, chemical or functional properties.

With respect to the exopolysaccharides, the instant specification has only provided the molecular weights and that they are soluble in water (see pp.11-12, example 4). The molecular weights are as follows: <EPS> 100,000 kDa and 50,000 kDa; <EPS> 100,000 kDa and 10,000 kDa; <EPS> 50,000 kDa and 3,000; <EPS> 10,000 kDa and <EPS> 3,000 kDa (pp.11-12, example 4). Additionally, it is known that the polysaccharide can make up the shape of a micelle and encapsulate an active agent for therapeutic utility.

(5) Method of making the claimed invention:

With respect to the lactobacillus strains claimed, there is no information on how to obtain the strains to make the claimed exopolysaccharide micelles.

With respect to the exopolysaccharides, it is known that they can be obtained from a consortium of bacteria or purified bacterial strains until a precipitate is formed (pp.10-12, examples 1-4). The micelles can be formed upon addition of 0.001% pyrene. It is not clear if this concentration is different for each of the EPS fractionated in example 4 and/or if this concentration is different based on the active agent added.

As stated *supra*, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable that claim(s) exopolysaccharide micelles are broad and generic, with respect to all possible compounds encompassed by the claims. The possible structural variations are limitless to any polysaccharide having the molecular weights mentioned above. Although the claims may recite some functional characteristics, the claims lack written description because there is no disclosure of a correlation between function and structure of the compounds beyond those compounds specifically disclosed in the examples in the specification. Moreover, the specification lacks sufficient variety of species to reflect this variance in the genus.

The description requirement of the patent statue requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See *In re Wilder*, 736, F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.") Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-6, 19, 29, 30 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "exopolysaccharide micelles comprising exopolysaccharide produced by a bacterium" in claim 1 renders the claim and its dependent claims 4-6, 19, 29, 30 and 40 herein indefinite. Neither the specification nor the claims provide any information on the structure of the polysaccharide. It is unclear if it is a homopolysaccharide or a heteropolysaccharide, if it is linear, or branched. It is also unclear how the monosaccharide units are glycosylated together, or how many of each monosaccharide is present.

The instant claims are product-by-process claims, and the patentability is determined by the product itself (see MPEP 2113). Because the specification does not provide guidance on how to obtain the claimed bacterial strains or the structure of the exopolysaccharide, one having ordinary skill in the art would not be able to ascertain the metes and bounds of the claimed product.

Maintained Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4-6, 19, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Simard et al., hereafter as the '131 publication (US Application Publication No. 2006/0057131, cited in previous Office Action).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The '131 publication discloses fermentation by-products produced from bacterial *Lactobacillus* strains R2C2, INIX, ES1 and K2 (claim 28). The '131 publication discloses the fermentation by-product comprises polysaccharides, including exopolysaccharides, hereafter EPS (paragraphs 0038-0039). The '131 publication discloses the protein containing the EPS is formulated at concentrations ranging from 0.001% to 1% (column 17, example 26, paragraph 0182), i.e. critical micellar concentrations identical to the instant disclosure (see instant specification, column 4, example 1, paragraph 0056). The '131 publication discloses the EPS containing protein is formulated with 5-fluoro uracil to treat colon cancer (column 20, example 37). Thus, the '131 publication discloses an EPS micelle, i.e. a "delivery system" comprising 5-FU,

wherein the EPS was produced by bacterial *Lactobacillus* strains R2C2, INIX, ES1 and K2.

The disclosure of the '131 publication anticipates claims 1, 4-6, 19, 29 and 30 of the instant application.

Response to Arguments

Applicant's arguments filed 30 September 2010 and the Declaration of Mr. Josée Beaulieu, submitted by Applicant on 30 September 2010 under 37 CFR §1.132 have been fully considered but they are not persuasive.

Applicant's declaration stating that the instant application and US Patent Application Publication No. 2006/0057131 both "stand in the name of Technologies Biolactis Inc." is insufficient to overcome a 102(e) rejection.

According to MPEP 2136.05: A 102(e) rejection can be overcome by antedating the filing date or by showing that the Application is by "other", i.e. the **inventors** listed on the prior art must be identical to the instant application.

Because the 1.132 declaration fails to show that the inventors are identical in the instant application as that of the '131 publication, the rejection is hereby **maintained**.

Conclusion

In view of the rejections to the pending claims set forth above, no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. BAHAR SCHMIDTMANN whose telephone number is 571-270-1326. The examiner can normally be reached on Mon-Thurs 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BAHAR SCHMIDTMANN/
Patent Examiner
Art Unit 1623